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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------------------|-----------------------------|
| 10/564,096 | 05/02/2006 | Rosario Lizio | 282276US0PCT | 7191 |
| 22850 7590 02/01/2008 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314 | | | EXAMINER WESTERBERG, NISSA M | |
| | | | ART UNIT 4173 | PAPER NUMBER |
| | | | NOTIFICATION DATE 02/01/2008 | DELIVERY MODE ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|---------------------------------|------------------------------|--|
| Office Action Summary | Application No. 10/564,096 | Applicant(s) LIZIO ET AL. | |
| | Examiner Nissa M. Westerberg | Art Unit 4173 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1 – 18 and 20 – 30, drawn to an oral multiparticulate pharmaceutical from comprising pellets.

Group II, claim(s) 19, 31 and 32, drawn to a process for producing an oral multiparticulate form.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the claimed subject matter does not constitute a contribution over the prior art and is therefore not a special technical feature. Claim 1 of the instant application recites a pellet pharmaceutical formulation designed for oral use wherein the pellets have an inner matrix layer with a peptide or protein active substance and a matrix polymer that is mucoadhesive. WO95/18602 (cited on PTO-1449) discloses pellets containing the synthetic peptide dDAVP (desmopressin). The peptide is encapsulated in microspheres less than 100 microns in diameter with excipients. The pellets are coated with enteric layer and

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packed into a capsule (p 6, ln 3 – 16). Possible excipients for the pellet with the dDAVP include microcrystalline cellulose co-processed with sodium carboxymethyl cellulose (P 13, ln 5 – 6). Sodium carboxymethyl cellulose is exemplified as a polymer having a mucoadhesive effect on p 12, ln 16 of the instant application. As to the specific dissolution and water uptake characteristics recited in the claim, it is assumed that this pellet formulation would fall within the limitations of the claim in the absence of information to the contrary.

Species Election

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

The active substance in the pharmaceutical form;

The components in the inner matrix and outer film;

The absence or presence of a separating layer between the inner matrix and outer film; and

The absence or presence of a lipophilic matrix embedded in the matrix having a mucoadhesive effect.

First Species Election Requirement

Applicant is required to elect the active substance present in the pharmaceutical formulation. Examples of acceptable species can be found in claims 10, 13, 16 and 24.

Second Species Election Requirement

Applicant is required to elect one specific composition of the inner matrix layer, including the polymer having a mucoadhesive effect in the inner matrix material.

Third Species Election Requirement

Applicant is required to elect the absence or presence of a lipophilic matrix in the matrix having a mucoadhesive effect. If the presence of a lipophilic matrix is elected, Applicant is further required to elect the component(s) of the lipophilic matrix. Examples of acceptable species can be found in claim 28.

Fourth Species Election Requirement

Applicant is required to elect the absence or presence of a separating layer between the active substance-containing matrix and the outer film coating layer.

Fifth Species Election Requirement

Applicant is required to elect the anionic polymer or copolymer present in the outer film coating.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner:

The presence of a lipophilic matrix is required in claims 20 – 32.

Specific active agents are exemplified in claims 10, 13, 16 and 24.

The presence of a separating layer is required in claim 18.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the protein or peptide active ingredient for this composition encompass a wide range of molecules of varying size, hydrophilicity/hydrophobicity, activity and other properties. The possible

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components for the polymer and lipophilic compounds encompass a wide range of compounds, all of which may not be capable of providing the characteristics claimed. Given the diversity of components encompassed by each of these groups, they are not so linked as to have the same special technical feature.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Joint Inventorship

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

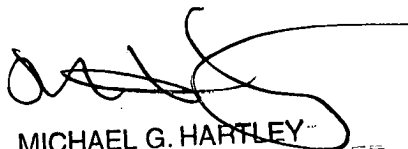
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NMW


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER